IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC., **Plaintiffs,** **v.** **MYLAN PHARMACEUTICALS INC.,** **Defendant.**	**Civil Action No. 1:17-cv-116-IMK**

POST-TRIAL REPLY BRIEF FOR MYLAN PHARMACEUTICALS INC.

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'514 patent	U.S. Patent No. 8,399,514
asserted claims	claims 1-4, 6, 8-13, 15, and 16 of the '514 patent
Biogen	plaintiffs Biogen International GmbH and Biogen MA, Inc., collectively
Br.	Biogen's responsive post-trial brief (ECF No. 377)
DMF	dimethyl fumarate
IPR	*inter partes* review
mg	milligram
MS	multiple sclerosis
Mylan	defendant Mylan Pharmaceuticals Inc.
Mylan Br.	Post-trial brief for Mylan (ECF No. 376)
POSA	person of ordinary skill in the art
PTAB or Board	Patent Trial and Appeal Board
PTO	United States Patent and Trademark Office
Tr.	transcript of bench trial (ECF Nos. 356, 358, 359, 362)
xx:*yy*-*zz*	column *xx*, lines *yy*-*zz*
§ ___	section of the Patent Act, 35 U.S.C.

INTRODUCTION

Biogen's brief predictably takes the same approach the Federal Circuit has consistently rejected. Biogen devotes dozens of pages attempting to divine written description support through scattered references to each claim limitation *individually*. Biogen has next to nothing to say when it comes to identifying support anywhere in the '514 patent's specification for the claimed treatment methods *as an integrated whole*. For that crucial analytical step, Biogen relies on amorphous "linkages" that allegedly tie together the specification's generic and disconnected disclosures to demonstrate possession of the "narrow and very specific procedure" (Br. 23) recited in the claims. To create that construct, Biogen contravenes both facts and law. First, Biogen repeatedly presumes disclosures that, in fact, appear nowhere in the specification. Second, Biogen focuses on what the *inventor allegedly knew* rather than what matters under the law: what Biogen *shared with the public* in the written description.

At bottom, the '514 patent's specification was written to describe drug-screening methods. The original inventor (Dr. Lukashev) included limited, generic references to treatment methods only to illustrate how drugs identified by his methods might eventually be used for treating any of myriad neurological diseases. Biogen contends it did not repurpose Dr. Lukashev's application, but the evidence leads to no other logical conclusion. Biogen received its Phase III trial results four years *after* the application was filed, and only then moved to add a new title, a new inventor, and all new claims directed to those new results. But to keep the application's 2007 priority date, Biogen could not amend the specification. The result was a gross mismatch between the '514 patent's specification and its narrow, specific method-of-treatment claims.

If the '514 patent's specification was genuinely meant to convey possession of specific, effective methods for treating MS by administering 480 mg per day of DMF, it certainly could and

would have said so. Instead, Biogen relies on disconnected references to each separate claim limitation buried amid generic treatment methods, which include a host of competing possibilities for the diseases to be treated and the drugs and dosage levels to be used. In particular, in the entire 28-plus column specification, a 480 mg dose of DMF is mentioned precisely *once*. And even then only as one bookend of one dose range among many others, with no reference at all to treating MS. That thin reed cannot bear the weight of validity Biogen piles onto it. This is especially so considering Biogen's repeated insistence to the PTO and multiple tribunals that skilled artisans would *not* have expected a 480 mg DMF dose to be effective in treating MS. Nothing in the specification comes close to dispelling that expectation. This Court should find the asserted '514 patent claims invalid for lack of written description.

ARGUMENT

I. No "added burden" applies to this or any other invalidity challenge

In reiterating the standard of proof for establishing invalidity, Biogen claims Mylan bears an "added burden" because written description allegedly came up during prosecution of the '514 patent. Br. 15-16. According to Biogen's theory, that creates an added burden of overcoming deference afforded to the PTO. *Id.* Biogen is wrong.

The same standard applies to all invalidity challenges. The Supreme Court has rejected calls for an invalidity standard "that would rise and fall with the facts of each case." *Microsoft Corp. v. i4i Ltd. P'Ship*, 564 U.S. 91, 109 (2011). The standard does not become "extremely clear and convincing evidence" or "crystal clear and convincing evidence" simply because an issue was previously considered by the PTO. *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012). Rather, the notion of deference to agency determinations is reflected in the ordinary "clear and convincing evidence" standard itself. *Id.* Biogen's suggestion of an enhanced burden goes instead to the practical observation that some factfinders may ascribe *more weight* to evidence

not previously considered by the agency. *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1350-51 (Fed. Cir. 2017). As a result, new evidence of invalidity that was not before the PTO may "'go further toward sustaining the attacker's unchanging burden.'" *i4i*, 564 U.S. at 110-11 (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)); *see also Sciele*, 684 F.3d at 1260 (same).

Here Biogen points to undeveloped statements by the examiner, made in support of obviousness rather than written-description rejections, to suggest that written description was already considered during prosecution. Br. 15 (citing JTX2173 at 388, 890-96). But Biogen elsewhere confirms that the PTO ended prosecution having "never made any rejection for lack of written description support." Br. 14. Biogen cannot have it both ways. In any event, the examiner's isolated, cryptic statements merit no special consideration. More importantly, the extensive arguments and testimonial and documentary evidence regarding written description developed at trial were *not* before the PTO and, if anything, are therefore due *added weight* toward sustaining Mylan's invalidity challenge. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000); *Sciele*, 684 F.3d at 1260.

II. Biogen's attempts at identifying written-description support depend on treating the asserted claims as a series of disconnected limitations

As Mylan explained in its opening brief, and Biogen does not dispute (*see* Br. 36-39), a patent's specification must demonstrate possession of each claim "as an integrated whole rather than as a collection of independent limitations" to satisfy the written description requirement. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013). Nevertheless, Biogen's affirmative written-description analysis focuses almost exclusively on addressing each claim limitation in isolation. Regarding the claimed methods as an integrated whole, Biogen offers only cursory and nebulous assertions—specifically, that the separate passages cited

for each individual limitation were somehow "link[ed]" through Method 4 in the specification. Br. 18-24. Biogen's ill-defined theory finds no support in the specification. And Biogen's effort to show disclosure of each limitation separately cannot substitute for disclosure demonstrating possession of the specifically claimed treatment methods as a whole.

A. Biogen's separate arguments about each individual limitation provide no support for the asserted claims as a whole

1. Treatment of MS

Biogen first attempts to establish that the '514 patent's specification focuses on MS "from beginning to end." Br. 18. But Biogen does not contend any cited passage demonstrates possession of the claimed methods for treating MS by administering 480 mg per day of DMF. And none does. For example, Biogen cites the title and abstract of the '514 patent. Br. 18. But the title was introduced in 2011 during prosecution and cannot provide written description support. DTX1656 at 11. Moreover, the abstract refers to MS only with respect to possible uses for *new* drugs identified via the disclosed screening methods, while therapeutic methods are described as directed more generally to "neurological disease." JTX2000 Abstract. Biogen also cites a background description of MS, but that discussion does not identify any treatment methods, much less the specific treatment methods using 480 mg of DMF recited in the claims. *See* Br. 18-19 (citing JTX2000 1:12-52).

Biogen also relies heavily on Method 4. Biogen posits that "discussions of Method 4 repeatedly emphasize that MS is *the neurological disease* targeted for treatment," Br. 19 (emphasis added), but that conclusion runs contrary to the underlying disclosures. In every instance, the specification describes Method 4 as targeted toward broad categories of neurological or demyelinating diseases, of which MS is just one of over thirty possibilities. JTX2000 8:24-28, 8:34-53, 3:1-4, 3:10-14, 4:30-38, 16:18-65; Tr. 300:4-301:11 (Lukashev). Biogen also suggests that Method 4 addresses the "hallmarks" of MS, Br. 19, but the patent's highly generalized description taught

that only "some embodiments" of Method 4 affect "at least one of" several pathologies, including but not limited to demyelination, JTX2000 8:39-51, 4:33-38. *Many* other neurological diseases, and even demyelinating neurological diseases, are described in the specification as potential targets for treatment. Biogen fails to acknowledge or address any of these facts. JTX2000 16:18-65. The specification's broad, generic sweep makes sense in the context of its primary focus on methods for screening and uncovering *new drugs* that could be valuable if effective against *any* neurological condition. Nothing about Method 4 is specific to MS, much less specific for treating MS with the specified drug at the dose recited in the asserted claims.

Biogen also highlights Example 3 of the '514 patent, which describes methods to test candidate drugs for Nrf2 activation using EAE mice. Br. 18, 20 (citing JTX2000 20:63-22:18); Tr. 413:5-415:14 (Greenberg); Tr. 291:8-292:23, 298:1-5 (Lukashev). As Mylan explained in its opening brief, Example 3 was not in the specification by the original filing date in 2007 and therefore cannot provide written-description support.[1] The inventors' testimony confirms the specification's three Examples are not related at all to the clinical treatment of MS. *See* § IV.B.2, *infra*; Tr. 414:11-415:14, 459:4-23 (Greenberg). Biogen points to portions of the specification that describe EAE mice as suitable for testing whether a compound can "slow or prevent neurodegeneration (including demyelination and neuronal death)." JTX2000 16:66-17:45. Consistent with Dr. Wynn's testimony, that indicates only that EAE mice could be used "for studying compounds," not for demonstrating efficacious treatments. Tr. 483:10-19 (Wynn); *see also* Tr. 413:1-415:14 (Greenberg).

[1] Biogen appears to suggest that including Example 3 by its later non-provisional filing date in 2008 could suffice for written description purposes. Br. 20 n.4. Biogen has consistently relied on the original 2007 priority date when combating prior art, so it cannot now shift to a later priority date for written-description purposes. *See Coal. for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01993, Paper 40 at 1 (PTAB June 22, 2016); ECF No. 376-1, App. 1, Ex. A at 4, 11-13.

Thus, even if considered, those references to EAE mice would at most indicate possession of methods for identifying compounds that might someday be used for treating at least one neurological disease. They do not demonstrate possession of specific methods for effectively treating MS using a specific dose of a specific drug, as claimed.

2. Treatment using DMF

Biogen next seeks to establish that the specification describes treatments using DMF. Br. 20-21. All of Biogen's citations, however, refer to DMF generally for use in treating generic neurological diseases, not at a specific dose for effectively treating MS. JTX2000 3:1-4, 4:29-32, 8:24-28, 8:34-53, 11:47-50, 18:58-62; *see also* Tr. 407:3-408:3 (Greenberg). Biogen also briefly invokes Examples 1-3, but those do not help either because they relate only to methods of screening for compounds capable of exhibiting the same activity as DMF (Nrf2 modulation), not methods of treating MS in a patient. Tr. 409:17-415:14 (Greenberg); *see also* § IV.B.2, *infra*. And as noted previously, Example 3 was absent from the specification when it was originally filed in 2007.

3. The 480 mg dose

Finally, Biogen turns to the claimed 480 mg dosage level. Br. 21-23. Biogen cites Method 4 and definitions for "therapeutically effective amount," but those disclosures do not identify a 480 mg dose. Instead, they generally reference neurological disease without specificity for MS, or even for demyelinating disorders. JTX2000 4:29-32, 5:52-59, 8:39-44. The lone reference to 480 mg anywhere in the '514 patent's specification occurs ten columns later and again includes no reference to MS or to the treatment of any particular disorder. JTX2000 18:62.

According to Biogen, the dosage range of 480-720 mg is the "narrowest, most preferred range" in the specification, and juxtaposing 480 mg as one end of a range also bound by 720 mg supposedly would have drawn a POSA specifically to a 480 mg dose. Br. 22. However, while 480-

720 mg is the narrowest disclosed range, it is not identified in any way as the preferred range and it is not "linked" to treatment of MS. JTX2000 18:52-64. More fundamentally, Biogen does not explain how the specification's single, bare reference to 480-720 mg conveys possession of methods specifically using a 480 mg dose for treating MS, particularly when the specification also presents 240 mg—a dose POSAs would have known to be ineffective for MS treatment—as equally "linked" to 720 mg. JTX2000 18:61; Tr. 522:9-22 (Wynn) (POSA would not believe 240 mg dose was effective to treat MS despite "linkage" to 720 mg dose). Biogen also does not dispute that the disclosed dosage information includes dosage amounts and factors influencing dosage selection that a POSA would have known were *inapplicable* to MS treatment. *See* Mylan Br. 18 (citing Tr. 512:22-514:21 (Wynn)); *see also* JTX2000 18:39-44; Tr. 520:17-522:8 (Wynn)).

B. Biogen's conclusory argument that the disparate citations are "linked" through Method 4 does not rescue the claims from invalidity

Despite lengthy discussions addressed to each separate limitation, Biogen's brief contains only a single paragraph directed to the ultimate issue: whether the specification demonstrates possession of the claimed methods—treating MS with DMF at 480 mg per day—as a whole. Br. 23-24. On that ultimate question, Biogen has very little to say and even less to cite from the specification itself—just a single, heavily edited quotation that refers to Method 4 but again says nothing about treating MS or using any specific drug dose. Br. 23 (quoting JTX2000 8:39-44). Biogen's conclusory assertions about "link[ing] these elements through treatment Method 4" cannot substitute for actual disclosure anywhere in the '514 patent's specification demonstrating possession of the "narrow and very specific" treatment methods recited in the claims.

In the entire specification, the 480 mg dose at the heart of the claimed methods appears *just one time*. That solitary reference to 480 mg, divorced from any discussion of MS treatment and buried without emphasis or further explanation in a range of dosage levels among a list of other

dose ranges, is the thinnest of reeds to bear the full weight of the '514 patent claims. "[T]here must be enough included [in the specification] to convince a POSA that the inventor possessed the invention." *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 17-9105 (SRC), 2020 WL 1151191, at *28 (D.N.J. Mar. 9, 2020). Here, the specification lacks disclosure to demonstrate actual possession of claims to effective MS treatment methods combining the recited limitations, particularly in view of the skepticism by those skilled in the art regarding doses below 720 mg.

C. Biogen's efforts to distinguish *Novozymes* are meritless

The Federal Circuit's core holding in *Novozymes* was that providing "formal textual support for each individual limitation" of a claim does not satisfy the written description requirement if the specification fails to describe the claimed subject matter as the unified whole "that those limitations together define." 723 F.3d at 1349. The specification must guide a POSA, having "no foreknowledge" of the specific method claimed, toward that particular method as one the patentee had actually described as his or her invention by the applicable filing date. *Id.* One cannot simply work backward from the claims and piece together "an amalgam of disclosures plucked selectively" from disparate portions of the specification. *Id.*

As Mylan has explained, this case matches *Novozymes* both in its facts and in the improper, reductionist approach to written description advanced by the patentee. Mylan Br. 20-23. In each case, a patentee motivated by post-filing developments introduced new claims into an old application disclosing a different invention. *See Novozymes*, 723 F.3d at 1340-43. In *Novozymes*, as here, each individual limitation of the new claims was expressly mentioned at least once in the original specification. *See id.* at 1341-42. And in each case, the patentee attempted to compensate for the specification's failure to describe those limitations together as an integrated whole by focusing instead on the disconnected disclosures of each separate limitation. *See id.* at 1345, 1349.

Biogen does not dispute those controlling principles. Br. 36-37. Nor did it take a different approach in its efforts to demonstrate sufficient written-description support. *See id.* at 18-24. Biogen instead advances unfounded factual distinctions and a series of straw-man arguments, but nothing changes the fundamental failure of the '514 patent's specification to describe the later-claimed treatment methods.

Biogen's purported factual distinctions do not meaningfully distinguish *Novozymes* and find no basis in the specification. To begin, Biogen suggests the '514 patent's claims differ from *Novozymes* because, it contends, "all elements of the claimed invention are explicitly disclosed with clear blaze marks and linked in the patent specification." Br. 37. All elements of the *Novozymes* claims were likewise explicitly disclosed, but that was not enough. 723 F.3d at 1349. As far as purported blaze marks and "links" in the specification, Biogen tellingly cites its own briefing rather than the '514 patent. Biogen further presumes disclosures that simply do not exist in the specification. Method 4 does not identify "a method of treating multiple sclerosis," Br. 37; it merely suggests generalized methods of treating *any* neurological disease using any of a wide array of compounds with at least some structural similarity to DMF. JTX2000 3:1-4, 4:29-38, 8:34-53. Nor does the specification teach "a preference" for treating MS or for using DMF (a known compound) over new drugs discovered through its screening methods, and it does not describe 480-720 mg/day as a "most preferred" dose range. *Compare* Br. 37, *with* JTX2000 16:18-65, 4:56-59, 9:22-53, 18:52-64.

Biogen's unfounded conclusion that "the invention is *specifically disclosed* and highlighted as preferred" cannot be squared with a specification that, at most, referred to each limitation individually and never described *any* method for treating any particular disease, using any particular drug, at any particular dose. Had the claimed methods been "specifically disclosed" as a unified

whole, as Biogen asserts, one would expect a supporting citation to show where that occurred. Biogen cannot provide one because none exists.

Biogen attempts to justify its approach of working backward from the claims to selectively pluck disclosures aligning with each claim limitation by asserting that "[a] proper written description analysis starts with the claims." Br. 37-38 (citing *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971)). That proposition is true as far as it goes, but it has no bearing here. Courts must know what a patent claim means to reach an informed conclusion about whether the specification supports it. *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354-55 (Fed. Cir. 2011) ("Claim construction is inherent in any written description analysis."); *Moore*, 439 F.2d at 1235 ("For this reason, the claims must be analyzed first in order to determine exactly what subject matter they encompass."). In *Moore*, the court had to decide an unresolved issue of claim construction before reaching the contingent written-description dispute. 439 F.2d at 1234-35. There is no unresolved construction here, *see* Br. 31 n.5, so *Moore*'s reference to claims being "analyzed first" is irrelevant.

Novozymes emphasized that written-description law requires assessing the specification from the perspective of "one with no foreknowledge" of the claims to determine whether the specification would have guided a POSA to the specifically claimed subject matter as something the inventor had actually invented by the time of filing. 723 F.3d at 1349. Just as in *Novozymes*, the specification of the '514 patent fails to describe any method that actually satisfies the claims. Nonetheless, Dr. Wynn took exactly the type of prohibited, hindsight-driven approach that was rejected by the Federal Circuit. *See id.* at 1349.

Biogen raises a series of other similarly irrelevant arguments. Mylan did not assert that all claim limitations must be "included in a single paragraph" or identified in the specification as "most preferred," or that inoperative embodiments "negate[ ] written description support." Br. 37-

39. What Mylan has asserted is that § 112 requires the specification to describe the claimed methods as a whole and "describe an invention understandable to a skilled artisan and show that the inventor actually invented the invention claimed." *Novozymes*, 723 F.3d at 1344 (alteration omitted); Br. 38 (quoting same). Because the '514 patent's specification fails to provide that necessary support as to its claims as a whole, those claims are invalid under *Novozymes* and § 112.

III. *Nuvo* confirms the invalidity of the asserted claims

Biogen's main response to *Nuvo* as binding precedent is an effort to cabin that case strictly to its particular facts. Br. 29 (describing *Nuvo*'s holding as "based on the facts in that case"); *see generally id.* at 29-34. Biogen correctly observes that *Nuvo* did not "change the basic principles of the written description law." Br. 29. Nor could it. Rather, *Nuvo* illustrated the correct application of those principles to a case closely resembling this one. Despite Biogen's desire to limit *Nuvo* to its precise facts, the Federal Circuit made its ruling precedential for a reason, and its guidance confirms the lack of written description for Biogen's asserted claims.

A. Biogen's narrow factual distinctions are immaterial to the fundamental principle that a POSA's background knowledge and expectations inform the written-description inquiry

In *Nuvo*, the Federal Circuit addressed claims to a drug formulation that required efficacy for achieving a stated functional effect—specifically, an uncoated proton-pump inhibitor (PPI) effective to raise gastric pH. *Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1379 (Fed. Cir. 2019). But the "record evidence demonstrate[d] that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective." *Id.* at 1380. Because the specification provided "nothing more than the mere claim that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work," the specification was "fatally flawed" and the claims were held invalid. *Id.* at 1381.

Biogen argues that *Nuvo*'s focus on the knowledge and expectations of a POSA is categorically inapposite here. According to Biogen, that is because the POSA's skepticism was "conceded by the patent specification" in *Nuvo*, while "there is no corresponding teaching in the '514 patent cautioning against the claimed 480 mg/day dose or indicating it would not be effective" and the specification in fact teaches that the 480 mg dose is "effective." Br. 30.[2] Biogen's superficial attempts to distinguish *Nuvo* miss on the facts and, more importantly, ignore the baseline legal principles illustrated in *Nuvo*'s analysis.

First, *Nuvo*'s holding did not turn on, and was not limited to, *what part* of the record indicated that POSAs would not have expected an uncoated PPI to work as claimed. What mattered was that POSAs would not have expected an uncoated PPI to work as claimed, irrespective of how that fact was established: "the *record evidence* demonstrates that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective." *Nuvo*, 923 F.3d at 1380 (emphasis added). Indeed, in *Nuvo* that conclusion was driven by *the patentee's own nonobviousness positions* invoking POSAs' skepticism and contrary expectations—just like in this case. *See* 923 F.3d at 1377 ("[T]he district court found upon Nuvo's insistence as part of its obviousness analysis that [POSAs] would not have expected uncoated PPIs to be effective ….").

Second, the '514 patent specification's generic statement that "an effective dose" may be any within a long list of ranges provides no basis to distinguish *Nuvo*. JTX2000 18:52-64. That cursory statement does not point specifically to a 480 mg dose among any of the other myriad dosage levels in those ranges, nor does the specification identify what such doses might be

[2] Biogen similarly asserts that "there was no teaching in the prior art that a 480 mg/day dose was ineffective," Br. 32, but Biogen's own arguments defy that contention. ECF No. 315-13 ¶¶ 89, 168 ("[I]n view of the prior art at the time of the invention, one of ordinary skill would not have selected a daily dose of 480 mg.").

"effective" for. Furthermore, *Nuvo* rejected similarly empty allusions to uncoated PPI being "effective." 923 F.3d at 1379-80. That did not suffice in *Nuvo*, and it does not suffice here.

Third, and most importantly, *Nuvo*'s reasoning is directly applicable. Biogen quotes the critical point: the *Nuvo* patents were invalid because the inventor chose to claim an effective treatment but did not adequately describe that efficacy "so as to demonstrate to ordinarily skilled artisans that he possessed and actually invented what he claimed," particularly where the POSA would not have expected that treatment to work. Br. 30-31 (quoting *Nuvo*, 923 F.3d at 1383-84).

So too here. The record contains considerable evidence that a POSA would not have expected the 480 mg/day dosage of DMF to treat MS as claimed, much of it from statements by Biogen's own witnesses, including Dr. Wynn, and by Biogen itself. Mylan Br. 14-15. Biogen responds by attempting to draw a distinction between "not having an expectation that a claimed invention will work" and having an expectation that it would "fail to achieve the claimed, desired result." Br. 31-33. Biogen has repeatedly asserted *unexpected results*—that a POSA would not have expected 480 mg/day DMF to effectively treat MS as claimed. *E.g.*, JTX2173 at 236 ¶ 14; Tr. 501:17-25, 502:8-23, 526:7-11 (Wynn) (POSAs would "not think to even study a 480-milligram dose" and efficacy was "especially surprising"); ECF No. 376-1, App. 1, Ex. A at 3; JTX2173 at 455. But an "unexpected result" does not mean a result achieved where POSAs had no prior expectation either way. It means a result *contrary* to what a POSA would have expected. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007) (explaining that properly evaluating whether something was unexpected requires considering "what properties *were* expected") (emphasis added). Accordingly, no daylight exists between (1) Biogen's consistent assertions that it would have been *unexpected* for the claimed treatments to *work*, and (2) *expecting* that the claimed

treatment would *not work*. Biogen's purported distinction makes no difference and provides no basis for distinguishing *Nuvo*.[3]

B. Biogen's arguments about "conflating" obviousness and written description ignore *Nuvo*'s central premise

Scattered throughout Biogen's brief is a recurring contention that evidence relevant to obviousness must remain separate from written description because, Biogen contends, obviousness concerns "the expectation of skilled artisans before reading the patent" while written description concerns what the "skilled artisan would understand after reading the patent." Br. 32; *see also id.* at 17, 27, 31-34, 39. Both doctrines, however, are assessed through the eyes of a POSA, and the POSA brings the same perspective—including the same background knowledge and expectations—to the table whether considering the prior art or considering the patent specification. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351, 1356-57 (Fed. Cir. 2010) (en banc) (written description analyzed from a POSA's perspective); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) (same, obviousness). Biogen itself confirms this, noting that written description must be analyzed "in the context of the state of knowledge at the time of the invention." Br. 28 (citing *Zoltek Corp. v. United States*, 815 F.3d 1302, 1308 (Fed. Cir. 2016), and *Capon v. Eshhar*, 418 F.3d 1349, 1357-59 (Fed. Cir. 2005)).

As an initial matter, Dr. Wynn conceded on cross examination that even *after* seeing the '514 patent specification, a skilled artisan still would not know that the 480 mg DMF dose was an effective MS treatment. Tr. 527:6-528:21 (Wynn). That should be a dispositive point. Regardless,

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[3] Biogen also attempts to distinguish *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332 (Fed. Cir. 2013), on grounds that *Synthes* purportedly "did not concern a skilled artisan's expectations about whether the claimed invention would work." Br. 31. Biogen misses the point. Mylan cited *Synthes* to confirm that evidence beyond the specification can inform whether claims lack adequate written description support in the eyes of a POSA. Mylan Br. 16.

the common thread of the POSA's perspective running through obviousness and written description guided the result in *Nuvo*. The Federal Circuit's written-description analysis expressly relied on facts established in the context of the patentee's nonobviousness case—namely, that a POSA would not have expected the drug formulation to be effective as claimed. *Nuvo*, 923 F.3d at 1374-75, 1377, 1380-81. In view of that background skepticism, the specification's limited, conclusory statements regarding efficacy were not enough to convince a POSA that the inventor had "actually invented what he claimed." *Id.* at 1380-81.

In the same way, the record evidence showing that a POSA would not have expected a 480 mg dose of DMF to treat MS illustrates the perspective a POSA would have brought when reading the specification and confirms the lack of sufficient written description. The '514 patent's single reference to the 480 mg dose appears among an extended list of other doses, stands apart from any mention of MS, and is found in a specification focused on drug screening that lacks *any* integrated description of the claimed method. That would not have sufficed to convince an already skeptical POSA that the inventor had actually invented and possessed the claimed MS treatment by the time of filing. It is inconceivable that the specification's single, disconnected, and unexplained reference to 480 mg would dispel all the POSA's skepticism and contrary expectations about that dose as an effective MS treatment.

If anything, legal standards differentiating obviousness from written description reinforce the *inadequacy* of the '514 patent's specification. To provide adequate written description for a claim, a patent's specification must provide *even more fulsome* disclosure of the invention than would be required in the prior art to render the same claim obvious. *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1378-79 (Fed. Cir. 2009); *Ariad*, 598 F.3d at 1352 ("[A] description that merely renders the invention obvious does not satisfy the [written description] requirement.").

Finally, Biogen's suggestion that *Nuvo* dooms "all non-obvious inventions" to invalidity for lack of written description makes little sense. Br. 33-34. Anyone that has truly devised an invention that would have been nonobvious to a POSA has the power to enlighten POSAs everywhere—regardless of POSAs' preconceived beliefs—*by fully describing the invention*. Moreover, an inventor seeking a patent has a statutory duty to do so under § 112 in return for the exclusive rights conferred by a patent. *See Ariad*, 598 F.3d at 1345 (disclosure is "the *quid pro quo* of a patent").[4]

C. Information not disclosed in the '514 patent's specification cannot provide written-description support and does not distinguish *Nuvo*

Biogen briefly attempts to distinguish *Nuvo* by arguing that Dr. O'Neill "had far more than a 'general concept'" of the invention, citing testimony purportedly showing Dr. O'Neill's "specific belief" in a 480 mg dose. Br. 36. But any such "specific belief" is irrelevant to establishing written description if not provided in the patent's specification, and the cited trial testimony pertains only to Dr. O'Neill's purported private statements. *See* § IV.A.1, *infra*; Tr. 565:12-15, 572:6-11 (O'Neill) (describing the 480 mg dose as a "hypothesis" that "could work"). In *Nuvo*, the inventor's testimony about having only a "general concept" of the invention confirmed that the specification lacked sufficient disclosure because the inventor admittedly lacked the necessary actual possession at the time of filing. *See* 923 F.3d at 1381. But the converse proposition does not hold. Testimony about Dr. O'Neill's private comments to colleagues at Biogen, even if true, would at most establish that he *could have* described the claimed MS treatment methods, but it says nothing about whether the *specification of the '514 patent* actually *did so*. Here, as in *Nuvo*, it did not.

[4] For all these reasons, Biogen's criticism of Dr. Greenberg for considering "evidence relating to the issue of the non-obviousness of the claimed invention" misses the mark. Br. 27.

D. Biogen cannot now distinguish its past arguments from the effective treatment of MS required by the claims

Biogen appears to argue that it can now disavow its prior assertions regarding unexpected results by suggesting that those statements, aimed at saving the asserted claims from obviousness, concerned one type of efficacy, while the claims now actually require something else. Br. 34-35. As explained in Mylan's opening brief, Biogen has repeatedly argued it was unexpected that 480 mg of DMF would effectively treat MS to overcome obviousness challenges against the asserted claims. Mylan Br. 13-16. Biogen cannot suddenly change course and distinguish between its own past arguments and the very patent claims those arguments were asserted to protect. *See New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (holding that judicial estoppel "prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase") (quoting *Pegram v. Herdrich*, 530 U.S. 211, 227 n.8 (2000)).

IV. Biogen's unfounded factual assertions and remaining flawed arguments provide no support for its position

Beyond its failed attempts to identify any written-description support for the claimed methods as a whole or substantively distinguish controlling Federal Circuit precedent, Biogen's brief contains a series of misstatements and legally erroneous arguments. Those additional issues are addressed briefly below.

A. Biogen's factual background reflects misplaced focus and misstates the record

Several aspects of the factual background presented in Biogen's brief warrant reply, including its emphasis on an inventor's subjective knowledge rather than the objective disclosures in the '514 patent, its revisionist narrative regarding its preferences for the Phase III trial, and its inaccurate description of the '514 patent's specification.

1. Compliance with the written description requirement depends on the content of a patent's specification, not on the separate knowledge or private statements of an inventor

Biogen goes into great detail regarding Dr. O'Neill's inventive process and purported advocacy for testing a 480 mg dose during internal deliberations at Biogen. Br. 1-9, 12; *see also id.* 33, 36.[5] But this is not an inventorship dispute. Dr. O'Neill's subjective beliefs and internal, private statements to other Biogen personnel have no bearing on the operative question here—whether the claimed treatment methods were adequately described to the public in the specification of the '514 patent. "[A]ctual 'possession' or reduction to practice outside of the specification is not enough. Rather … it is the *specification itself* that must demonstrate possession." *Ariad*, 598 F.3d at 1351-52 (emphasis added).

The Federal Circuit's decision in *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293 (Fed. Cir. 2015), frequently cited by Biogen (at 1, 16, 17), is more supportive of Mylan. There the court found "the district court erred by relying on [an] undisclosed clinical protocol to support its written description determination" because the protocol was "not part of the specifications of the asserted patents. It should not form the basis of the written description inquiry, even if it shows that the inventors had invented the claimed invention before the time of filing. The written description requirement requires possession *as shown in the specification*, not as shown by prior experimental work." *Id*. at 1309. Thus, for example, Biogen's reliance (at 3-4) on Dr. O'Neill's "insight into an effective dose of DMF for treating MS" as a result of an undisclosed confidential due diligence review is entirely irrelevant to written description.

[5] After receiving IPR obviousness decisions in its favor before the second day of trial, Biogen removed Dr. O'Neill (and Dr. Dawson) from its witness list and refused to present them for live trial testimony.

2. Biogen's suggestion that it always planned to use a 480 mg dose during Phase III trials conflicts with its contemporaneous statements and behavior

Biogen's background discussion suggests it always planned to include the 480 mg DMF dose in its Phase III trial, regardless of the FDA's request to do so. Br. 8-10. That is inconsistent with the record. Every record citation Biogen offers to demonstrate that it had "begun preparations" for testing the 480 mg dose before meeting with the FDA ties back to the same one thing: a single mathematical calculation Biogen performed to determine how many additional patients would be required if its test protocols were adjusted to include a 480 mg dose. Br. 9; *see* JTX2091 at 2; JTX2100 at 2; JTX2133 ¶37; JTX2013 ¶¶ 94, 98; Tr. 689:11-690:15, 691:18-692:12 (Dawson); Tr. 374:1-20 (Bozic); Tr. 671:21-672:9, 653:24-654:19 (Lansden). Beyond that limited, pen-and-paper exercise, Biogen has failed to identify any other contemporaneous evidence of plans or preparations to test 480 mg before the FDA required it.

Furthermore, the record shows that Biogen viewed the 480 mg dose as a "contingency plan" if the FDA was not satisfied with testing only the 720 mg dose (as Biogen preferred). JTX2100 at 2. At the time, Biogen described the calculations it relies on here as determining the necessary study size "*if* a 480mg dosing arm *needs to be added* to the Phase 3 protocols" or "*if* [a] 480mg dosing arm *is required*." JTX2142 at 1-2; *see also* JTX2091 at 2. Even after the FDA encouraged Biogen to include the 480 mg dose, Biogen resisted and maintained that its original design testing 720 mg alone remained the best choice. PTX108 at 7-8; *see also* DTX1584 at 8-9 ("Changes required" as a result of August 2006 FDA meeting included adding 480 mg/day testing arm); JTX2044 at 5-6. The record shows that Biogen never included a 480 mg dose in its own Phase III proposals to FDA and pushed back against the agency's suggestion before ultimately relenting. Biogen's current rationalizations cannot change the contemporaneous record.

3. Biogen erroneously asserts that the '514 patent's specification disclosed using DMF at 480-720 mg per day "to treat MS"

Biogen's factual background barely addresses the content of the '514 patent itself. Br. 10-11. Nevertheless, that brief discussion fundamentally misstates the specification's disclosures. For one, Biogen represents that its earliest priority application included "specific disclosure of using 'from about 480 mg to about 720 mg per day' DMF *to treat MS*." Br. 11 (citing JTX2182 at 2, 36) (emphasis added). But the cited pages of the application make no mention of MS or any other disease, JTX2182 at 2, 36, nor does any other part of the application provide the "specific disclosure" that Biogen casually imputes. Biogen similarly overstates the application's disclosure by declaring that it described 480-720 mg as the "most preferred" dose range. Br. 11 (citing JTX2182 at 36). The cited text does not identify any dose range as preferred—it lists a series of "example" dose ranges while teaching that a doctor may determine appropriate dosage. JTX2182 at 36. And Dr. Wynn admitted that "from reading" the specification "I don't know that 480 would be the preferred dose for treating MS." Tr. 525:15-25. Those wishful depictions in Biogen's "factual background" are emblematic of Biogen's repeated efforts to recast and reimagine the actual disclosures of the '514 patent—throughout its brief here, and ever since receiving the Phase III trial results during prosecution.

B. Biogen's remaining scattered criticisms are meritless

As explained above, the asserted claims are invalid under binding Federal Circuit precedent, including *Novozymes* and *Nuvo*. Biogen's handful of remaining arguments are insubstantial, factually inaccurate, and legally flawed.

1. Biogen repurposed its drug-screening application four years after it was filed

Biogen insists it did not repurpose the '514 patent application, but simply "amended the claims during prosecution, as is very common." Br. 14, 24. That counterfactual argument drastically understates the wholesale makeover the application received after Biogen learned the results of its Phase III trials. As originally filed, the application had a title ("Nrf2 Screening Assays and Related Methods and Compositions"), a single inventor (Dr. Lukashev) and claims that were devoted to drug-screening methods. DTX1656 at 11 (amending title); DTX1016 at 5 (inventor Lukashev); JTX2182 at 40-42; PTX401 at 35-37; DTX1016 at 40-42 (original claims). All this changed four years *after* the application was originally filed, once Biogen had its Phase III trial results in hand. The title became "Treatment for Multiple Sclerosis," Dr. O'Neill was added as an inventor, and all claims were replaced with new ones focusing narrowly on a specific dose (480 mg) of a specific drug (DMF) to treat a specific disease (MS). DTX1656 at 11; DTX1657 at 13-18; DTX1656 at 2-4. It is true, as Biogen notes, that the patent specification "remained unchanged during prosecution." Br. 24. But that is the very point. To maintain the application's 2007 priority date, Biogen could *not* amend the specification. As a result, Biogen wound up with a fundamental disconnect between the 2007 specification, focused on drug-screening methods, and the 2011 claims, addressed narrowly to a very specific treatment method. That clear repurposing resulted in a lack of written description and invalid claims.

Biogen argues that the 2007 specification always described the "claimed methods of treating MS" and the purportedly surprising efficacy of a 480 mg DMF dose. Br. 22, 25. But as Biogen itself notes, Dr. Lukashev, the only named inventor from 2007 to 2011, testified that he is not a skilled artisan with respect to treatment methods, and his only contributions "related to [drug] screening methods." Br. 25; Tr. 277:8-278:5 (Lukashev). For his part, Dr. O'Neill testified that he

could not recall any involvement with the application before 2011. Tr. 565:16-566:1, 579:13-16, 580:7-9 (O'Neill). If Dr. Lukashev contributed no treatment methods, and Dr. O'Neill had no involvement with the application until 2011, then how could the 2007 specification show possession of an effective MS treatment using 480 mg of DMF? More pointedly, if the inventors genuinely intended to describe that specific MS treatment, why would they have done so in this roundabout way—mentioning a 480 mg DMF dose *once* in the entire 28-plus column specification, and then as just one endpoint of a single dose range among many other dose ranges in a passage that makes no mention of MS? That "would be a highly elliptical, cryptic way to communicate possession" of the claimed treatment method, one indicative of a lack of written description. *Quake v. Lo*, 928 F.3d 1365, 1376 (Fed. Cir. 2019) (no written description where two isolated statements in a 30-plus column specification provided "(at most) faint 'blaze marks'" to the claimed method).

2. Dr. Lukashev's testimony is relevant to written description

Biogen argues that Dr. Lukashev's testimony "does not bear on" written description. Br. 25-26. Not so. Biogen argues that Dr. Lukashev is not a skilled artisan "*with respect to the claims at issue*," but it does not dispute that he researched DMF's "mechanism of action" and that his "inventive work related to the screening methods disclosed in the '514 patent." *Id.* (emphasis added). Significantly, Biogen continues to rely on Example 3 involving the EAE animal model to supply written-description support for the claimed treatment methods. Br. 20-21. Biogen's expert Dr. Wynn also relied on Example 3 extensively at trial. Tr. 483:20-484:19, 509:4-11, 512:11-17 (Wynn). But it was Dr. Lukashev—not Dr. O'Neill—who provided the information for all three Examples in the patent. Tr. 288:11-23 (Lukashev). Dr. Lukashev testified that Examples 1-3 were directed to understanding DMF's mechanism of action. Tr. 290:21-291:24 (Lukashev). He also testified unequivocally that Examples 1-3 did not involve the clinical treatment of MS, had

"nothing to do with the efficacy in clinical disease," and gave no indication that DMF would be effective for treating MS at any particular dose. Tr. 291:25-293:2 (Lukashev).

Dr. O'Neill's testimony was equally unequivocal. He "did not design or carry out the[ ] experiments" in Examples 1-3, and he could not recall the experimental data in the specification itself or say whether it shed any light on therapeutically effective dosing of DMF in humans. Tr. 560:5-16, 561:3-8, 562:8-14, 563:23-564:6 (O'Neill). Instead, Dr. O'Neill testified that he relied on data he reviewed when conducting confidential due diligence associated with Biogen's acquisition of the Swiss company Fumapharm—data that were *not* disclosed in the patent specification. Tr. 564:15-21, 588:17-589:14 (O'Neill); *see also* § IV.A.1, *infra*. The inventors' own testimony thus directly contradicts Biogen's (and Dr. Wynn's) continued reliance on Example 3 to show written-description support for a 480 mg dose of DMF to effectively treat MS. *See Nuvo*, 923 F.3d at 1381 ("Although inventor testimony cannot establish written description support where none exists in the four corners of the specification, it illuminates the absence of critical description in this case."); *Sanofi-Aventis*, 2020 WL 1151191, at *27 (relying on inventor testimony in finding lack of written description).

3. Mylan does not "demand more than written description law requires"

Biogen argues incorrectly that Mylan applies the written description requirement too stringently. Br. 26. In fact, Mylan's analysis tracks precisely what Federal Circuit law requires: an inventor must "convey[ ] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate[ ] that by disclosure in the specification." *Nuvo*, 923 F.3d at 1376 (citations and internal quotations omitted); *Sanofi-Aventis*, 2020 WL 1151191, at *24-25, 28. The "essence of the written description requirement is that a patent applicant … must describe his or her invention so that the public will know what it is *and*

that he or she has truly made the claimed invention." *Nuvo*, 923 F.3d at 1376-77 (citation omitted, emphasis added). To be sure, "experimental data demonstrating effectiveness" or a "theory or explanation of how or why a claimed composition will be effective" are not required. *Id*. at 1380. Nevertheless, "[a]lthough examples are not always required to satisfy the written description requirement, the lack of any disclosure of examples may be considered when determining whether the claimed invention is adequately described." *Boston Sci. Corp. v. Johnson & Johnson*, 674 F.3d 1353, 1364 (Fed. Cir. 2011). And as *Nuvo* makes clear, where "the specification provides nothing more than the mere claim that" a treatment method "might work, even though persons of ordinary skill in the art would not have thought it would work, the specification is fatally flawed." 923 F.3d at 1381. That is the case here. *See* § III, *infra*.[6]

4. Biogen's criticisms of Dr. Greenberg are baseless

Biogen criticizes Dr. Greenberg because he allegedly "did not consider 'therapeutically effective dose' or 'therapeutically effective amount' [as] defined in column 5, lines 52-59" of the patent, which Biogen argues include the concepts of "demyelination, axonal loss, and neuronal death." Br. 27. Biogen is wrong. Biogen cites a single snippet from Dr. Greenberg's testimony, in which he agreed that in his direct examination, "we didn't call out th[e] specific paragraph" at column 5, lines 52-59. Tr. 440:24-441:10. But Biogen simply ignores multiple instances where Dr. Greenberg testified that the specification fails to disclose therapeutically effective amounts of

[6] Biogen's reliance on *Alcon Research Ltd. v. Barr Laboratories, Inc.*, 745 F.3d 1180 (Fed. Cir. 2014) is off point. There, the specification "detail[ed] the claimed invention and provid[ed] a step-by-step description" of how skilled artisans could use it; provided "exemplary formulations"; "disclose[d] data generated by the inventor," including comparisons to "more commonly used" products; and described dozens of "preferred examples" of the relevant compositions. *Id*. at 1191. Moreover, in that case the district court erred by conflating enablement and written description, and the patent challenger "adduced no evidence, let alone clear and convincing evidence, that was probative" of the written description requirement. *Id*. at 1191-92. None of that is true here.

DMF to treat MS—including by reducing demyelination, axonal loss, and neuronal death. *See, e.g.*, Tr. 406:23-408:2 (Greenberg) (discussing Method 4 and noting "it goes on to indicate that you would 'administer to the mammal a therapeutically effective amount of at least one neuroprotective compound which has,' and it outlines the formulas. And then it repeats the notion of slowing neurodegeneration, *specifically talking about demyelination, axonal loss, and/or neuronal death*," and concluding there "is not any indication of a therapeutically effective amount.… It's setting up a notion of how you would screen agents, as I read this … but it doesn't define a dose as therapeutically effective for multiple sclerosis"); *see also id.* 414:11-415:14, 459:4-23 (no efficacy data in Example 3: "[T]here's no clinical scoring of the mice presented. There's no pathology of demyelination. There's no pathology of axon loss. There's no measuring of the immune system's impact on the nervous system. All there is is taking the mouse and showing that the Nrf2 pathway could change … that's different than the model showing a therapeutically effective dose."). Biogen cannot try to impeach Dr. Greenberg by ignoring large swaths of his testimony.

CONCLUSION

Biogen's arguments cannot compensate for the fundamental failure of the '514 patent's specification to support the drastically different claims Biogen introduced years after filing. The Court should find those claims invalid for lack of written description under § 112.

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CERTIFICATE OF SERVICE

I hereby certify that on the 17th day of April, 2020, I filed the foregoing "Post-Trial Reply Brief for Mylan Pharmaceuticals Inc." with the Clerk of the Court using the CM/ECF system of the Court which will cause notice thereof to be served on the following counsel of record via email:

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